Preliminarily, Applicants traverse the §112 argument. The claims as filed are clear and definite, as required by §112. However, in an effort to move the application forward, Applicants have amended claims 1 and 8 to more clearly provide the antecedent basis of the elements identified by the Examiner. Applicants do not believe that these rejections narrow the scope of claims 1 and 8.

With respect to the rejection of claims 1-8 over Song et al., Applicants believe that the rejection is erroneous because of several difference between the device in Song et al. and Applicant's device. Song is not directed to a safety device. Song et al is directed to a injection needle set that can be used to provide repeated injections at several different injection sites on a patient.

The Song et al device includes a metal needle 9 attached to a plunger rod 5 that can be displaced back and forth within a cylindrical housing 3. A flexible injection tube 12 is attached to the forward end of the housing. After inserting the needle 9 and injection tube 12 into a patient, the plunger 5 is displaced rearwardly so that the needle is displaced into the housing 3. Subsequently, the injection tube is removed from the patient, and can be re-extended so that the needle and injection tube can be re-inserted into the patient at a different point on the patient's body.

The injection tube 12 is designed to prevent bacterial contamination of the needle 9 during use. The injection tube 12 does not provide any type of safety feature to protect the needle 9. In fact, as mentioned above, the needle can be re-extended after use. Clearly such a device does not prevent inadvertent contact with a contaminated needle since it does not have a lock to lock the needle in a retracted position to prevent inadvertent exposure to a contaminated needle, and since the needle is clearly designed to be re-exposed for further use after the initial use.

Intended Use

lock in dependent claim

In contrast, Applicants' device uses a shield or sheath that provides protection for the sharpened tip of the needle. The needle is retracted, preferably into the shield, so that the shield protects the needle to prevent inadvertent contact with the

contaminated needle. In addition, preferable, the shield is configured such that the needle and the shield can be inserted into the patient and the needle and shield can remain in the patient even after the needle is retracted into the shield. Song et al. does not teach or suggest a device have such a combination of features.

The Official Action indicates that Song et al. teaches a biasing element 5. This is not correct.

The element 5 in Song et al. refers to the rod or plunger 5 that is manually displaceable in the cylindrical housing 3 by pushing or pulling on the plunger 5. There is no teaching of a biasing element for biasing the needle rearwardly, such as a spring as disclosed in several of Applicants' embodiments in this application.

spring dependent claim

The Official Action also indicates that Song et al teaches a needle retainer releasably retain the needle against the rearward bias of the biasing element. Again this is not correct.

Since Song et al. does not use a biasing element to bias the needle rearwardly, the Song et al. device does not need a needle retainer, and there is no teaching or suggestion of such an item. In fact, the Official Action does not even refer to a portion of the specification or a reference number for an element that teaches such a needle retainer. Instead the Official Action makes the bare assertion that Song et al. teaches a needle retainer. However, as mentioned above, Song et al does not teach or suggest a needle retainer because the device operates quite differently from Applicants' device, and because Song et al. does not teach or suggest a device with a needle retainer.

Further, Song et al. does not teach or suggest a device in which the needle is retracted into a shield as recited in claims 1 and 8. As shown in Fig. 4, in Song et al. the needle 9 is manually pulled rearwardly into the inner housing 3. The needle 9 does not stay in the injection tube 12. For this additional reason, claims 1 and 8

are patentable over Song et al.

Still further, Song et al. does not teach or suggest a shield that is substantially puncture resistant. As discussed previously, Song et al. is directed to a different type of product. The Song et al. device is directed to prevent bacterial contamination by using an injection tube that overlies the needle during insertion of the device into the patient. Song et al is not directed to a safety product.

Applicants' have designed a safety product that includes a novel shield that is substantially puncture resistant. Song et al does not teach or suggest using a puncture resistant shield. In fact, Song et al. stress that the injection tube 12 should be as thin as possible. See page 6, line 3. Since the injection tube in Song et al. is not designed to sheath the needle to protect against inadvertent needle sticks, there is no motivation to make the injection tube puncture proof.

In light of all of the shortcomings in the Song et al reference, Applicant's respectfully request that the Examiner reconsider the rejection of claims 1 and 8. Applicants also request that the Examiner favorably consider newly presented claims 9-20. These dependent claims are patentable for at least the reasons set forth above in connection with claims 1 and 8. In addition, claim 9 recites a lock for locking the needle in the retracted position. Song et al. does not teach or suggest such a lock, because a lock would be completely contrary to Song et al's purpose of providing a needle that can be re-used for addition punctures in a patient as discussed above. For this additional reason, claims 9 and 13 are further patentable over Song et al.

Further claims 2 and 5 are patentable over Song et al. Claim 2 specifically recites the step of inserting the shield and needle into the patient and retracting the needle into the shield. As discussed previously, Song et al does not tech or suggest retracting the needle into the shield . Song et al. teaches retracting the needle all the way back into the cylindrical housing 15. Accordingly, claim 2 is patentably

distinct from Song et al. Therefore Applicants request that the Examiner reconsider the rejection of claim 2. For at least the same reasons, Applicants request that the Examiner reconsider the rejection of claim 5, along with dependent claims 17-20.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this Response and accompanying papers are being deposited on **October 16, 2002** with the United States Postal Service as first-class mail in an envelope properly addressed to COMMISSIONER OF PATENTS AND TRADEMARKS, Washington, DC 20231

October 16, 2002
Date of Certificate

Stephen Eland

Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of **ONE** month beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

October 16, 2002
Date of Certificate

Stephen H. Eland
PTO Registration No. 41,010

ATTACHMENT A

1. A medical device, comprising:

a hollow housing;

a needle having a sharpened tip projecting forwardly from the housing;

a biasing element biasing the needle rearwardly;

a needle retainer releasably retaining the needle against the rearward bias of the biasing element

a flexible shield fixedly attached to the housing, projecting forwardly from the housing;

the shield <u>having a forward edge and</u> being configured for insertion into a patient;

the shield sheathing the needle such that in ~~the~~ <u>a</u> projecting position, the sharpened tip of the needle projects beyond the forward edge of the shield, and in ~~the~~ <u>a</u> retracted position the sharpened tip is enclosed within the shield;

wherein upon actuation of the needle retainer, the biasing element displaces the needle rearwardly so that the sharpened tip of the needle is enclosed within the shield, wherein the shield is substantially puncture resistant wherein the axial force required to buckle the shield is less than the force necessary to puncture the shield with the needle to prevent inadvertent contact with the contaminated needle.

2. A method for infusing fluid into a patient with a medical device having a needle <u>and a shield</u>, comprising the steps of:

inserting the needle <u>and shield</u> into the patient;

~~shielding~~ <u>retracting</u> the needle <u>into the shield while the shield is in the patient</u>; and

infusing fluid through the shielded needle into the patient.

5. A method for transfusing one of blood and plasma in or out of a patient with a

medical device having a needle and a shield, comprising the steps of:

inserting the needle and the shield into the patient;

~~shielding~~ displacing the needle rearwardly such that the needle is disposed within the shield in the patient; and

transferring said one of blood and plasma through the shielded needle while a portion of the device is inserted in the patient.

8. A medical device, comprising:

a hollow housing;

a needle having a sharpened tip projecting forwardly from the housing;

a biasing element biasing the needle rearwardly;

a needle retainer releasably retaining the needle against the rearward bias of the biasing element

a shield fixedly attached to the housing, projecting forwardly from the housing;

the shield having a forward edge and being configured for insertion into a patient;

the shield sheathing the needle such that in ~~the~~ a projecting position, the sharpened tip of the needle projects beyond the forward edge of the shield, and in ~~the~~ a retracted position the sharpened tip is enclosed within the shield;

wherein upon actuation of the needle retainer, the biasing element displaces the needle rearwardly so that the sharpened tip of the needle is enclosed within the shield, wherein the shield is substantially puncture resistant wherein the axial force required to buckle the shield is less than the force necessary to puncture the shield with the needle to prevent inadvertent contact with the contaminated needle.